

**REMARKS**

**I.**

**SUPPORT FOR CLAIMS 17-44 INCLUDES THE FOLLOWING:**

CLAIM	SPECIFICATION PAGE NUMBER	PARAGRAPH
17/31	1 3-4 6 8 10 12 14 original claim 9	1 1 <sup>st</sup> full paragraph 1 1 and 2 2 1 2
18/32	16	1 <sup>st</sup> partial paragraph Support for claim also lies in original claim 9 on Page 32
19/33	4	1 <sup>st</sup> full paragraph
20/34	8	Last paragraph
21/35	9	Last paragraph
22/36	9	Last paragraph
23/37	10	1 <sup>st</sup> full paragraph
24/38	10	1 <sup>st</sup> full paragraph
25/39	10	1 <sup>st</sup> full paragraph
26/40	10	1 <sup>st</sup> full paragraph
27/41	10	2 <sup>nd</sup> full paragraph
28/42	10	2 <sup>nd</sup> full paragraph
29/43	10	2 <sup>nd</sup> full paragraph
30/44	12 14	1 <sup>st</sup> full paragraph 1 <sup>st</sup> full paragraph

## II.

### THE CLAIMED INVENTION IS CLEARLY ENABLED UNDER 35 USC 112 FIRST PARAGRAPH

As indicated above, the present claims are clearly supported in the specification. Thus, this same support for these claims enables these claims to be carried out by those skilled in the art upon reading this specification. The procedure is not complex, although it is novel and non-obvious. The procedure is clearly described, the idea of course, being that paraffin-embedded, formalin fixed tissues or the like are incubated in a hot aqueous solution containing a certain amount of surfactant as well as a tissue activating agent. The extent of time spent in the hot solution is inversely proportional to the temperature of that solution. Those that are skilled in the art upon reading the specification would know quit well that as in most procedures of these types, washing the processed tissue samples with ordinary buffered solutions would be an appropriate step prior to immuno staining.

The present invention is simple and easily carried out by those skilled in the art. Various concentrations of surfactant are seen in the original claim 9, as well as in the various trial runs on pages 20-24. That the present invention is enabled and is even more clearly established by the fact that compositions of the present invention are currently popular on the market and have less directions then the ample description in the present patent application. Those using this product to enhance the immuno stainability of formalin-fixed paraffin-embedded tissues are excited about the effectiveness of the present procedure and composition.

### III.

THE PRESENT INVENTION IS NEITHER ANTICIPATED NOR RENDERED  
OBVIOUS OVER ANY OF THE ART CITED BY THE EXAMINER OR KNOWN TO THE  
APPLICANT.

The original claim 1 was rejected under 35 USC 102b as anticipated by Thorne (U.S. 5,552,294), if necessary in like Cattoretti et al. Applicant points out that new claim 17 not only has a preamble defining intended use, but also describes a solution that has a temperature of at least 80°C. This hot solution with surfactant removing agent and a tissue activating agent is clearly distinguished from anything suggested in Thorne or Cattoretti (or any other references).

Many of the first claims were rejected under 35 USC 103a in view of the Hazelbag et al., Shi, et al and Yorukoglu et al., and if necessary further in view of Norton et al., or Miller, et al. Applicant points out that Thorne et al., does not include a detergent (Polymyxin B being an antibiotic). Applicant also points out that neither of the above cited references utilizes a surfactant to enhance the immunostainability of formalin fixed paraffin embedded tissue. Certainly neither one has the surfactant and 80°C temperature as seen in claims 17 and 31. Applicant respectfully requests that the present claims be entered and examined in view of these comments.

In the previous Office Action a variety of claims were rejected in view of references such Ding et al., Prieto and Yorukoglu et al. Some of these references eliminate the deparafinization solvent step and instead heat paraffin-embedded formalin-fixed tissue with a buffer solution and then transfer the tissue to a second hot buffer solution. No surfactant is suggested. Hazelbag, et al., describe the use of microwave heating deparafinization treatment for the immuno staining of certain components of formalin fixed paraffin-embedded tissue. No surfactants are mentioned or used.

Thorne et al., describe the use of a pressure cooker for superheating paraffin-embedded formalin fixed tissue in the presence of pH 6.0 citrate buffer. The results of the immunostainability retrieval were believed comparable to those obtained with a microwave oven heating. No surfactant was utilized. Miller et al., also utilized a pressure cooker for similar purposes. No surfactants were involved and this reference merely seeks to point out the advantages of a pressure cooker over a microwave oven. Various other references were previously cited refer to surfactants, but none refer to surfactant-induced immunostainability, to surfactant solutions of the same temperature and general composition as those claimed herein. The Shi et al. references again describes microwave heating as a component of antigen retrieval for immunostaining of previously formalin fixed paraffin-embedded sides. The influence of pH as well as monoclonal antibodies are recognized.

Applicant requests entry of this Preliminary Amendment as well as consideration and allowance of claims 17-44. Should the Examiner have any questions and suggestions to aid in the appropriate resolution of this matter, a telephone call to the Applicants undersigned representative at his desk phone of (210) 228-2408 is requested.

The present claimed invention is entirely unsuggested by any art cited and is fully enable. Applicant also has established secondary considerations such as market penetration and customer satisfaction which can be shared with the Examiner at a future interview if this is desirable.

Should any fees greater than the enclosed check be due, the Commissioner is authorized to deduct such fees from deposit account number 07-2400.

Respectfully submitted,

By

  
Daniel S. Hodgins, Ph.D Reg. No. 31,026

**JACKSON WALKER L.L.P.**

112 E. Pecan Street, Suite 2100

San Antonio, TX 78205

Tel: (210) 978-7700

Fax: (210) 978-7790

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Elva J. Abundis

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